

## REMARKS

Claims 124-129 are pending in this application. Claims 124 and 127 are amended for clarity. Therefore, no new matter is introduced. The Office Action is discussed below:

### ***Anticipation Rejection and Response to Arguments:***

On pages 2-5 of the office action, the examiner maintains the alleged anticipation rejection and asserts that claims 127-129 do not specify the order of process of irradiating and heating steps. Applicants respectfully disagree with the examiner and point out that claims 127-129 clearly recite processes for preparing an orthopaedic implant prosthesis. For additional clarity of the recited method steps, applicants amend claims 124 and 127.

The examiner also asserts that claims 127-129 when interpreted as claiming melting before irradiation are entitled to a filing date of 02-13-1996 and when interpreted as claiming irradiation before melting are entitled to a filing date of 10-02-1996. Accordingly, the examiner maintains the rejection of claims over Hyon *et al.* Again, applicants disagree with the examiner and reiterate that Hyon has a section 102(e) date of May 6, 1996, which is after the earliest filing date of the instant application. Applicants submit that the instant application claims priority to U.S. Application Serial No. 08/726,313 (filed October 2, 1996), which was filed as a continuation-in-part of U.S. Application Serial No. 08/600,744 (filed February 13, 1996). Therefore, the Hyon patent, having May 6, 1996 as the 102(e) priority date, does not qualify as prior art under 35 U.S.C. § 102(e), because instant application's initial filing date antedates Hyon's filing date.

Applicants also submit that the instant originally filed specification (filed February 13, 1996) has support for a method of crosslinking by irradiation and heating after irradiation. Applicants refer to the original specification (see Example 6 on pages 44-46, for example) and indicate that the thermal treatment was continued through the irradiation process of cross-linking, including after each dose of irradiation. Applicants

also refer that the specification discloses, for example, a total dose of 5-20 Mrad at a dose rate of 2.5 Mrad per pass and it takes at least two passes of irradiation while the polymer is thermally treated after each dose of irradiation (see for example, Example 9 at pages 48-49). This is further evidenced by the fact that the van de Graaff generator used at the time generated a dose rate of 2.5 Mrad per pass. Therefore, the polymer according to the claimed invention is produced by cross-linking and heating after each irradiation.

Furthermore, applicants refer to the above discussion that a patent applicant need not show completion of every embodiment of an invention in a Rule 1.131 declaration\*. Applicants refer that the declaration of Merrill *et al.*, filed June 8, 2007, contains data showing the completion of both the MIR and CISM embodiments of the invention prior to January 20, 1995.

In view of the above, Hyon *et al.* patent is not a prior art to the claimed invention. Applicants also mention that the Hyon *et al.* patent, however, is Section 102(e) prior art against the '158 patent.

Regarding the evidence in the Declaration of Merrill *et al.*, filed June 8, 2007 under Rule 1.131, the examiner agreed that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995, wherein the polyethylene is first melted and then irradiated (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example). Hence, a method that involves irradiation is followed by subsequent melting to treat a polyethylene preform was reduced to practice before January 20, 1995. Accordingly, Hyon is not a prior art to the claimed invention.

On pages 2-5 of the office action, the examiner also maintains the rejection and alleges that claims 124-129 are anticipated by Dijkstra *et al.* According to the examiner, the species of claims 127-129, wherein the UHMWPE preform is melted and then

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\* As explained by the Court of Customs and Patent Appeals in *In re Fong*, 288 F.2d 932, 936 (CCPA 1961), a 131 declaration is sufficient if it shows a species of an invention.

irradiated, is also disclosed by Dijkstra *et al.* The examiner believes that Dijkstra *et al.* disclose a process for crosslinking UHMWPE in the melt comprising heating a preform in a nitrogen atmosphere at 200°C with electron beams. The examiner admits that Dijkstra *et al.* do not mention an orthopaedic implant prosthesis bearing, however, opined that the phrase "for preparing an orthopaedic implant prosthesis bearing...resistance" is a statement of future intended use that is not of patentable weight with respect to the claimed process steps. Again, applicants disagree with the examiner and reiterate that a method of making orthopaedic implant prosthesis bearing using heat treatment and subsequent irradiation or irradiation of UHMWPE is nowhere found in the Dijkstra *et al.* publication. Dijkstra discloses a process for making bar stocks of polyethylene and does not relate to a method for making an orthopaedic implant to be used within a body according to the claimed invention. Therefore, Dijkstra *et al.* publication is not relevant to the claimed invention.

The examiner also asserts on page 4 of the Office Action Dijkstra *et al.* disclose process steps corresponding to those set forth in the instant claims, thus, the process steps would be expected to provide a preform from which bearings having improved mechanical properties and increased wear resistance are to be fabricated, as set forth in the instant claims to define the future intended use of the process of treating the preform. Again, applicants refer to above discussion that a method of making orthopaedic implant prosthesis bearing using heat treatment and irradiation of UHMWPE is nowhere found in the Dijkstra *et al.* publication.

Applicants also submit that the claimed method of making orthopaedic implants is not expressly or inherently disclosed in Dijkstra *et al.* In this regard, applicants refer the examiner to MPEP § 2131 (Rev. 5, August 2006) that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Accordingly, the Dijkstra does not anticipate the claimed invention. Withdrawal of the rejection is therefore solicited.

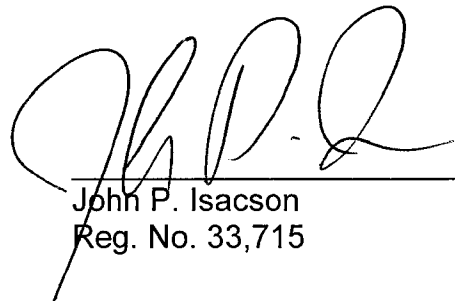
***Double Patenting Rejection:***

On pages 5-7 of the office action, the examiner maintains the provisional rejection of the claims 124-127 under the judicially created doctrine of obviousness-type double patenting and alleges as being unpatentable over claims 124-129, 131-134, and claims 124-125, 130, 143-146 of co-pending application serial nos. 10/197,209 and 09/764,445, respectively. In response, applicants reiterate, because applicants have not received any notice of allowance for the '209 or the '445 applications, the merits of this provisional rejection need not be discussed by at this time. See MPEP § 822.01 (August 2001).

**REQUEST**

Applicants submit that claims 124-129 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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